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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,539	10/17/2003	Joel S. Echols	32328US02	1150

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EXAMINER
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KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1612

MAIL DATE	DELIVERY MODE
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01/22/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/688,539

**Applicant(s)**

ECHOLS ET AL.

**Examiner**

Gollamudi S. Kishore, Ph.D

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The amendment dated 12-31-07 is acknowledged.

Claims included in the prosecution are 1-6.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The distinction between the hydrophilic polymer and the polyvinyl acetate and polyvinyl alcohol in claim 1 is unclear.

Applicant's arguments on page 5 of the response have been fully considered but are not persuasive. The issue here is the distinction between the generic hydrophilic polymer and the specific polymers recited. The claims do not recite polyvinyl acetate, polyvinyl alcohol and a hydrophilic polymer other than these two.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (6,132,751) in combination with Guy (5,540,930) and Holly (4,883,658).

Suzuki discloses emulsion compositions for eyes drops. The compositions contain water, phospholipids such as lecithin, polyvinyl alcohol, polyvinyl pyrrolidone, isotonizing agents such as glycerol and solvents such as ethanol (col. 4, line 17-26, col. 6, lines 54-67, col. 7, lines 33-44, Examples).

Guy discloses eye formulations. The formulations contain water, PVP, PVA, glycerol and Tween 80 (col. 3, line 10 through col. 4, line 19).

Holly while disclosing ophthalmic solutions for treatment of dry-eye syndrome teaches that the combination of an aqueous solution of a partially hydrolyzed polyvinyl acetate and polyvinyl alcohol is synergistic. The compositions further contain polyvinylpyrrolidone (abstract, col. 3, line 51 through col. 5, line 27, examples and claims).

To include a surfactant such as Tween 80 in the formulations of Suzuki would have been obvious to one of ordinary skill in the art since Guy who teaches ophthalmic formulations teaches the use of a non-ionic surfactant such as Tween 80. The addition of polyvinyl acetate in Suzuki would have been obvious to one of ordinary skill in the art since the combination of polyvinyl acetate and polyvinyl alcohol is synergistic as taught by Holly.

Applicant's arguments have been fully considered, but are not persuasive. Applicant argues that Suzuki's examples indicate the use of either polyvinyl alcohol or polyvinyl pyrrolidone but not together. Applicant also argues that Guy does not teach a

combination. These arguments are not persuasive. First of all, the independent claim recites only 'hydrophilic polymer' and not polyvinyl pyrrolidone. Secondly, as pointed out before, one of ordinary skill in the art would be motivated to use polyvinyl alcohol and polyvinyl acetate together with polyvinyl pyrrolidone because Holly teaches such a combination and also teaches the synergistic effect of polyvinyl alcohol and polyvinyl acetate. Applicant argues that Holly does not disclose that by mixing polyvinyl acetate and polyvinyl alcohol it is possible to lower the surface tension of the solution while forming a completely wettable adsorbed layer over hydrophobic surface. According to applicant, this is disclosed in Holly as being beneficial in increasing tear film stability, instability of the tear film being a problem the Holly patent is concerned with. This argument is not persuasive since instant claims are composition claims and motivation to use the combination need not be the same as applicant's. Applicant's arguments that there is no motivation to combine Holly with Suzuki are not persuasive since one of ordinary skill in the art would benefit from the advantages taught by Holly in Suzuki since both are drawn to the eye treatment compositions. Applicant's arguments that at least some of the dependent claim limitations are not met by the prior art (phospholipid is formulated in polysorbate 80, glycerol, ethanol and water are not persuasive since as pointed out above, instant claims are drawn to compositions and whether these components are added to the phospholipid or added separately, the final product will be the same and applicant has not shown that to be otherwise. The prior art is suggestive of the use of these claimed components. With regard to the removal of ethanol in Suzuki, the examiner points out that instant claims do not recite any specific amounts of

ethanol and applicant has not shown any unexpected findings resulting from the presence of ethanol.

5. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (6,132,751) in combination with Guy (5,540,930) and Holly (4,883,658) as set forth above, further in view of applicant's statements of prior art.

The teachings of Suzuki, Guy and Holly have been discussed above. Suzuki in particular teaches the use of lecithin, glycerol, ethanol and water.

Applicant on page 6 of the specification state that the combination of lecithin, ethanol, glycerol, polysorbate 80 is readily available in the market under the trade name Amisol. One of ordinary skill in the art would be motivated to use Amisol since it already contains premixed lecithin, ethanol, glycerol and polysorbate 80, the individual components taught by Suzuki and Guy in particular.

applicant's arguments have been fully considered, but are not persuasive. The examiner has already addressed the arguments regarding Suzuki, Guy and Holly. Applicant argues that just because that the combination is readily available in the market under the trade name Anisol, does not mean that it would have been obvious to use that product in that claimed combination. This argument is not persuasive. The prior art is suggestive of the use of these components in eye formulations and therefore, one of ordinary skill in the art would either combine these individually or use a readily available product and avoid the step of mixing the individual components.

**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Gollamudi S Kishore, Ph.D  
Primary Examiner  
Art Unit 1612

GSK